

### **REMARKS**

Upon entry of this amendment, claims 19-23, 25-28, 30-34, and 37-39 will be pending. Claims 37-38 are withdrawn. Claims 35-36 have been canceled herein without prejudice. Claim 39 is new.

Claim 19 has been amended to clarify the definition of R<sup>12</sup> to specifically include NR<sup>18</sup>R<sup>19</sup> as shown on page 10, lines 10-11 of the specification as originally filed. Claim 19 has also been amended to correct the structure of formula (I) which was incorrectly represented in Applicants response to the previous office action. The incorrect representation was done without deceptive intent on the part of the Applicants and has been corrected herein. A typographical error also has been corrected in claim 19. New claim 39 is directed to a preferred compound of claim 19, support for which is found on pages 10-11 of the specification as originally filed.

Claims 37 and 38 have been amended to recite methods of treating colon cancer, breast cancer, ovarian cancer, epidermoid cancer or prostate cancer. Support for this amendment can be found throughout the specification as originally filed as well as in the experimental data provided in the Declaration under 37 C.F.R. 1.132 provided in connection with the Applicants response to the previous office action. Specifically with respect to the data obtained for the following cell lines: HT-29, A2780, KB-3-1, L929, and MCF-7.

Amendment and cancellation of the claims herein is not/are not to be construed as acquiescence to any of the rejections/objections set forth in the instant Office Action and were done solely to expedite prosecution of the application. Applicants hereby reserve the right to pursue the claims as originally filed or similar claims in this or one or more subsequent patent applications.

Applicants respectfully thank the Examiner for withdrawal of the rejections under 35 U.S.C. §102(b) and 35 U.S.C. §103(a).

**Claim Rejections – 35 U.S.C. § 112, first paragraph**

Claims 19-34 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to enable compounds wherein n is 2, 3 or 5. The Examiner states that the starting materials and how to make the non-piperidinyl compounds “are not seen but required.”

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *U.S. v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). The examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *Manual of Patent Examining Procedure* (“MPEP”) § 2164.04 (citing *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993)).

Accordingly:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must be taken as being in compliance with the enablement requirement* ... unless there is a *reason to doubt the objective truth of the statements* contained therein which must be relied on for enabling support

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It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

*Id.* (emphases added).

Applicants respectfully submit that whether or not the scope of a claim is broad is irrelevant to the assessment of the enablement of the claim. The question is whether those skilled in the art would have been able to make and use the claimed invention based on the disclosure. (*See U.S. v. Telectronics, Inc.*, at 785).

Applicants respectfully submit that the pending claims are enabled because the specification "contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented." *Id.*

For example, the specification discloses representative preparative methods throughout the examples, as well as schematic methods for which one of ordinary skill in the art could readily make the compounds of the claimed invention. Specifically with regard to starting materials, Applicants draw attention to paragraphs [0064] and [0065] of the printed publication of the present application (US 2005/0239713) wherein it is stated that compounds of formula (IV) can be assembled through peptide coupling of commercially available and known amino acids.

Indeed, Applicants assert that one of ordinary skill in the art would recognize the corresponding amino acids which are needed to prepare compounds according to claim 19 wherein  $n = 2, 3$  or  $5$  are simple amino acid building blocks (e. g. the corresponding building block wherein  $n = 3$  is N-Methylproline).

As such, Applicants respectfully assert that sufficient guidance is provided in the specification so as to allow those of ordinary skill in the art to make and use the claimed invention. Indeed, the claimed invention is directed to the use of obtainable compounds and the skilled artisan can readily determine the starting materials for the compounds

encompassed by the claims by using the simple amino acid building blocks disclosed. Moreover, the determination of starting materials is a routine one that every skilled artisan is prepared to make, and which requires little or no effort. Therefore, Applicants respectfully submit that one reasonably skilled in the art could make or use the invention as claimed without undue experimentation.

In sum, Applicants respectfully submit that: (1) the specification provides sufficient information and guidance to those of ordinary skill in the art to make and use the claimed invention; (2) the Examiner did not provide any factual or legal basis to doubt that the claims are enabled; and (3) to the extent any experimentation is necessary, such experimentation is not undue.

Moreover, without acquiescing to the grounds for the rejection, the present claims have been amended to further define and clarify the preferred features of the invention.

Therefore, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

#### **Request for Rejoinder of Method Claims**

Claims 37-38 relate to methods of treating a patient comprising one or more compounds of claim 19. As such, method of use claims 37-38 are commensurate in scope with the present compound claims. Since a search for the compounds of claim 19 will necessarily result in all uses of any such compounds, and as Applicants believe that claim 19 is presently in condition for allowance, Applicants respectfully request rejoinder of method of use claims 37-38 in accordance with M.P.E.P. 821.04 and *In re Ochiai*, 71, F.3d 1565 (Fed. Cir. 1995).

With regard to the potential for rejection of claims 37-38 under 35 U.S.C. 112, first paragraph, as described above, claims 37 and 38 have been amended to recite methods

of treating colon cancer, breast cancer, ovarian cancer, epidermoid cancer or prostate cancer. Support for this amendment can be found throughout the specification as originally filed as well as in the experimental data provided in the Declaration under 37 C.F.R. 1.132 provided in connection with the Applicants response to the previous office action. Specifically with respect to the data obtained for the following cell lines: HT-29, A2780, KB-3-1, L929, and MCF-7. As such, Applicants believe amended claims 37-38 fully meet the requirements of 35 U.S.C. 112, first paragraph, and are suitably proper for rejoinder.

### **CONCLUSION**

In view of the amendments and remarks made herein, Applicants submit that the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are respectfully requested. If a telephone conference with Applicants' representative would be helpful in expediting prosecution of the application, Applicants invite the Examiner to contact the undersigned at the telephone number indicated below.

### **FEE AUTHORIZATION**

Applicants request a one-month extension for filing the within response. The Director is authorized to charge the extension fee, the RCE fee and any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to Deposit Account No. 04-1105, under Order No. 62661(52171).

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